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N491 N518 N55X N550 N566 N58X N58Y N593 N602
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(54) **A film construction for an ostomy pouch**

(57) An ostomy pouch may have each of its walls made from a laminate of

a) a heat or RF weldable plastics film (A),
b) an adhesive (B),
c) a vapour-deposited metal or glass layer (C) not exceeding 10 microns and preferably less than 3 microns in thickness, and
d) a thin coating layer (D).

A method of making a film laminate for use as an ostomy pouch wall comprises laminating together a plurality of plastics film layers, vapour-depositing a metal or glass layer on a smooth polymer film (SPF), joining the said plurality of plastics film layers to the metal or glass layer, removing the smooth polymer film and replacing it by a further laminate of a plurality of plastics film layers.

FIG.5.

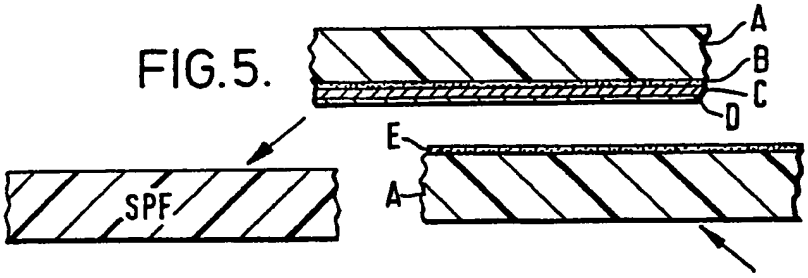

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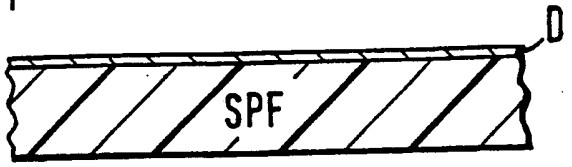
FIG.1.



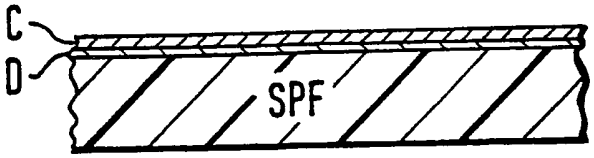
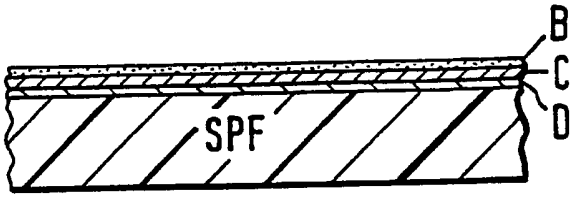


FIG.2.

FIG.3.



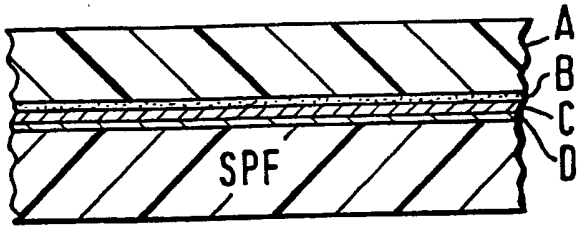
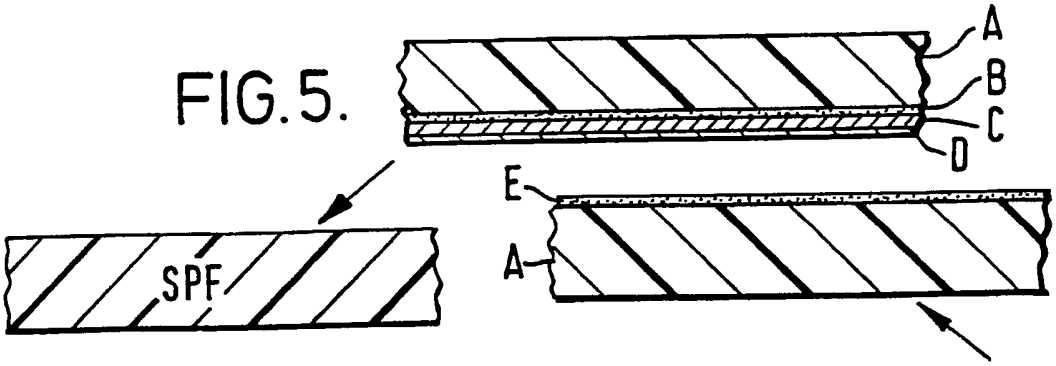


FIG.4.

FIG.5.



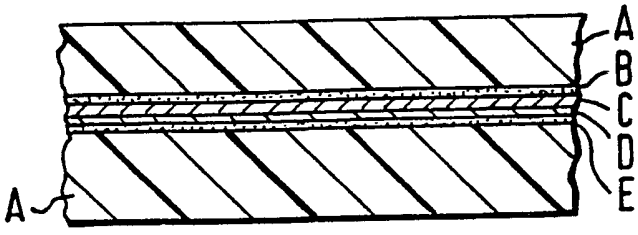


FIG.6.

A FILM CONSTRUCTION FOR AN OSTOMY POUCH

This invention relates to a film for making ostomy pouches, and a method of making such a film.

The film used for the production of ostomy pouches has to possess certain properties for the end-product to meet functional requirements and patient (wearer) acceptance. These properties include:-

1. Mechanical strength such that the pouch does not fail in service due to tearing, creep, etc.

2. The film must be weldable in order to form a pouch. The resultant bond must have adequate strength to ensure that the pouch does not burst or leak during usage.

3. It must provide an adequate barrier against odour emanating from body waste. These gases can escape by transmission through various known types of film, whereas the preferred route is to pass them through a deodorising filter.

4. It must be comfortable for the patient to wear, and to be essentially free of rustle characteristics when the patient moves or sits.

Laminated and co-extruded films meeting the above criteria have been developed over a number of years. A polymer which often has been utilised to provide the desired gas barrier properties of the aforesaid films is a copolymer of polyvinylidene chloride. However, in recent times there has been a move towards environmental improvements, and it is therefore a desire to eliminate chlorine-containing polymers from the pouch films. There are alternative polymers which are capable of providing an adequate gas barrier when the moisture content of the polymer is low. Examples include polyvinyl alcohols (PVOH), ethylene vinyl alcohols (EVOH) and polyamides (nylons). When an ostomy pouch is used it is subjected to moisture on the inside from body waste, and on the outside there is sweat. Also the temperature of the bag approaches that of the body and these three factors when combined have the effect of reducing the performance of the bag in terms of barrier properties to an unacceptable level, when the bag is worn for extended periods.

Examples of materials which have virtually perfect gas barrier

properties are metals and glass. However, unless these materials are exceptionally thin, that is to say of thicknesses of a few microns, they would be too rigid, and hence not meet the other requirements for an ostomy pouch, notably the comfort and noise aspects. The use of vacuum-deposited aluminium as one of the layers in an ostomy pouch has been suggested in British Patent Application No (GB-A) 2 201 372. The present invention is based on the concept of depositing very thin films of metals or glasses onto a smooth polymer film surface, to yield products having excellent gas barrier characteristics. The two most commonly used materials are aluminium and silicon dioxide. In packaging applications, but not in ostomy film laminates, one smooth film used is polyester. A disadvantage of the so-called metallised polyester as manufactured for packaging of foods etc., is that the composite films made in this way are either too rigid or too noisy to make them acceptable for use in an ostomy pouch. These problems are overcome by using a thin deposited layer of a material possessing excellent barrier characteristics incorporated in a novel manner into a film structure and subsequently used to form an ostomy pouch.

According to the invention in its broadest aspect, a film laminate for use as an ostomy pouch wall is made by laminating together a plurality of plastics film layers, vapour-depositing a metal or glass layer on a smooth polymer film, joining the said plurality of plastics film layers to the metal or glass layer, removing the smooth polymer film and replacing it by a further plurality of plastics film layers.

In a particular embodiment of the invention, a film laminate for use as an ostomy pouch wall is made by (i) applying a thin coating layer (e.g. a lacquer) onto a smooth polymeric film such as polyester, (ii) applying on top of said coating layer a thin (thickness less than about 5 microns) film of metal or glass, (iii) applying thereto one or more layers of plastic film of which at least one is a film as defined herein as Layer A, (iv) separating the smooth polymer film from the laminate formed in step (iii), and (v) uniting the exposed surface of the resulting laminate with a further Layer A as defined herein.

An advantage of the manufacturing procedure described herein is that the integrity of the thin metal or glass film, and hence its gas barrier property, is preserved by depositing it on a plastic film of great smoothness and then covering it with a lacquer. However, the step of peeling off, or otherwise removing the smooth polymer film and replacing it with e.g. an e.v.a. film, is needed because polyester films and other films of equivalent smoothness, cannot be satisfactorily heat or RF welded to each other.

The present invention aims to use the barrier properties capable of being achieved with a thin coating of either a metal, e.g. aluminium or glass. In combination with other coatings and adhesives, this thin metal or glass layer is bonded between two thicker polymeric films. Such films may themselves be laminates. The laminated film will then possess both excellent barrier properties and with the correct choice of polymer layers as set out below, be weldable, mechanically strong, and essentially rustle-free.

According to one embodiment of the invention, there is provided a film laminate for use in an ostomy pouch, the laminate comprising at least four layers, herein called layers A, B, C and D, whose compositions and characteristics are as set out below.

Layer A

A thermoplastic film which is capable of being welded to itself using, for example RF or impulse bonding techniques;

- has sufficient strength to support a load of 2kg per 15cm width;
- is soft and flexible;
- shall produce a noise less than that exhibited by a Wall Street Journal when rustled at ambient temperature and humidity;

said film being made from any one or more of:

- ethylene vinyl acetate having a vinyl acetate content of 5 to 15% by weight;
- ethylene acrylic acid copolymer;
- polyethylene;

Polyethylene co-polymers with:

- vinyl acetate

- ethyl acrylic acid
- methacrylic acid
- polybutenes
- polyurethane
- polyvinyl chloride [plasticised].

Layer B

An adhesive suitable for bonding layers A and C together; e.g. a polyurethane adhesive.

Layer C

A thin deposited coating of metal, e.g. aluminium, or glass e.g. silicon dioxide constituting a gas barrier and having a thickness such that when creased or folded the oxygen transmission rate therethrough is not more than 40ml per square metre per 24 hours at 38°C.

Layer D

A thin coating layer, e.g. a lacquer designed to readily release the bond between itself and a subjacent layer.

According to another aspect of the invention, two further layers, one called Layer E and defined below, and the other being Layer A as herein defined, may be added, yielding a laminate having six layers A, B, C, D, E, A. Such a laminate makes a particularly satisfactory wall for an ostomy pouch.

Layer E

An adhesive suitable for bonding together layers D and A, e.g. a polyurethane adhesive.

The following is a summary of the important features of a preferred method of making a film for an ostomy pouch. This comprises the steps of:

providing a smooth layer of a polyester to form a temporary substrate;

coating Layer D thereonto;

coating Layer C onto layer D;

coating Layer B onto Layer C;

placing the resulting laminate onto Layer A material, so providing a five-layer laminate; then peeling off the polyester and

attaching instead Layer A material so achieving a transfer of the A-D laminate from the polyester substrate to a substrate (Layer A) which is weldable to other components such as an ostomy coupling flange or a deodorising filter.

One example of a manufacturing method according to a preferred embodiment of the invention will be better understood from the following description, given with reference to the accompanying drawings, in which:-

Figure 1 is a diagrammatic illustration of a smooth polymer film (SPF) upon one surface of which has been placed Layer D, that is, a coating layer, for example a lacquer, designed to readily release the bond between itself and the layer SPF. Layer D is cast onto the smooth polymer film using a suitable technique such as gravure, reverse roll coating, or other known method;

Figures 2-6 inclusive are further diagrammatic illustrations of stages in the method.

Onto the Layer D there is deposited using a known vacuum deposition method, a thin coating layer C of a metal e.g. aluminium or glass e.g. silicon dioxide. As seen in Figure 3, onto layer C is applied a layer B of adhesive to provide a bond to a layer A which is added to form a five-layer laminate as seen in Figure 4. The next step, seen in Figure 5, is to peel the layer of smooth polymer film (SPF) off the lacquer layer D and bring into contact with the exposed surface of the layer D a separate laminate comprising Layer A as defined above and Layer E, also as defined above. The resulting six-layer laminate is seen in Figure 6.

The thickness of Layer A may vary. It may for example be a value in the range of up to about 70 microns. Layer B may be 2 to 2.5 microns, Layer C 0.1 micron, Layer D 3 to 5 microns, and Layer E 1.8 to 2.3 microns. It is important to employ a smooth polymer film, preferably polyester, as a temporary substrate, in order to achieve the desired ready separation between the SPF layer and the Layer D.

In a preferred embodiment of the invention, the ostomy pouch film described may have only four layers, namely the four Layers A, B,

C and D as shown in the upper part of Figure 5. In this event, the thickness of Layer A would be about 50 to 70 microns. This particular form of film would be useful either if it were required that only one surface of the film need be heat weldable by a plastics welding tool, and/or the nature of Layer D was suitable and adequate to serve as a support to which is attached an ostomy pouch filter. Conventional processes used to prepare Layer A include extrusion and casting.

As will be understood, Layer D is a smooth, thin coating which has some adhesion to the SPF. After Layers A, B, C and D are added thereto as seen in Figure 5, the resulting four-layer laminate is capable of being separated as a unit from from the smooth polymer film; that is, the smooth polymer film is peeled off from Layer D, as seen in the left-hand part of Figure 5. As mentioned, the preferred material for the SPF is polyester. It is preferred that the surface of layer D is receptive to printing thereon.

It will be appreciated that the thicknesses of the components in the laminated film are such that it has adequate strength in terms of mechanical properties. For example, in a film laminate as shown in the upper part of Figure 5, Layer A would be at least about 60 microns thick whereas for a laminated film as shown in Figure 6, each of the layers A might be about 30 microns thick.

The polymer which constitutes Layer A could be made by a conventional method, in which the polymer is first melted and fed to an orifice by means of a screw mechanism. It is then fed through a die which may for example be a slot die. The film from the slot die is then passed over a chill roll and is then in its cast form.

The coating (Layer D) is deposited as a liquid and is then changed from a liquid to a solid by, e.g.

- removal of solvent by heating;
- removal of water in an emulsion by heating;
- by cross linking by heat or radiation (e.g. electron beam, ultra violet).

The coating is such as to have a low bond strength to the substrate (SPF) and yet can be removed by peeling. The coating may usefully

also have properties of receiving printing and being heat sealable.

A feature of this invention is the temporary use during the manufacturing process of a smooth polymer film to receive the layers D, C, B and A. If, for example, an extruded film were to be used instead, this would be found to have too rough a surface and hence, after layer C was applied, would yield a product with inferior properties, (e.g. tendency to cracks, discontinuities) compared to the quality of composite laminate achieved with a temporary substrate constituted by a smooth polymer film such as polyester. If an extruded film were to be used a substantial coating would have to be applied.

It will be realised that there has been disclosed herein a novel and useful laminated film for use in making an ostomy pouch, and a method for making same.

While the present disclosure has referred to the preferred materials, thicknesses, and manufacturing steps to be employed, it will be appreciated that in the alternative, other materials, thicknesses, and manufacturing steps may be employed.

Claims

1 An ostomy pouch film which comprises a laminate of

a) a heat or RF weldable plastics film,

b) an adhesive,

c) a vapour-deposited metal or glass layer not exceeding 10 microns and preferably less than 3 microns in thickness, and

d) a thin coating layer.

2. An ostomy pouch film which comprises a laminate of:

a) a heat or RF weldable plastics film,

b) an adhesive,

c) a vapour-deposited metal or glass layer not exceeding 10 microns and preferably less than 3 microns in thickness,

d) a thin coating layer,

e) an adhesive, and

f) a heat or RF weldable plastics film.

3. A method of making a film laminate for use as an ostomy pouch wall comprising laminating together a plurality of plastics film layers, vapour-depositing a metal or glass layer on a smooth polymer film, joining the said plurality of plastics film layers to the metal or glass layer, removing the smooth polymer film and replacing it by a further laminate of a plurality of plastics film layers.

4. An ostomy pouch film according to Claim 2 in which the film referred to in (f) is the same as that referred to in (a).

5. An ostomy pouch film according to Claim 1, 2 or 4 in which the adhesive (b) and/or (e) is a polyurethane adhesive, and the layer referred to in (c) is vapour-deposited aluminium.

6. An ostomy pouch film according to Claim 1, 2, 4 or 5, in which the said thin coating layer is a film of lacquer.

7. A method according to Claim 3 in which the smooth polymer film is polyester employed as a temporary substrate.

8. A method of making an ostomy pouch film substantially as hereinbefore described and illustrated.

9. An ostomy pouch film substantuially as hereinbefore described.

10

Patents Act 1977 **CORRECTED COPY**
Examiner's report to the Comptroller under Section 17
(The Search report)

Application number
GB 9414268.4

Relevant Technical Fields

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(ii) Int Cl (Ed.5) B32B 15/08, B32B 17/10, A61F 5/445, A61L 25/00

Search Examiner
R J MIRAMS

Date of completion of Search
21 OCTOBER 1994

Databases (see below)
(i) UK Patent Office collections of GB, EP, WO and US patent specifications.

(ii) ONLINE DATABASES

Documents considered relevant following a search in respect of Claims :-
1 to 9

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&: Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages		Relevant to claim(s)
A	GB 2201372 A	(SMITHS) whole document	
* X	GB 2069409 A	(KONINKLIJKE EMBALLAGE) eg page 3 lines 39 to 42	1, 6
	* correction		

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